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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/646,939	11/14/2000	Conor Mulrooney	7146-106	1308

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EXAMINER

CHUNDURU, SURYAPRABHA

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 12/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/646,939	<b>Applicant(s)</b> MULROONEY, CONOR	
	<b>Examiner</b> Suryaprabha Chunduru	<b>Art Unit</b> 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 04 October 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-18 and 20-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 and 20-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

1. Applicants amendment and the response to the office action, filed on September 23, 2004 has been entered and considered.
2. Claim 19 is cancelled. Claims 1-2, 20-22 are amended. New claims 25-26 are added. Claims 1-18, 20-26 are pending.

***New Grounds of rejections***

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-18, 20-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Walker et al. (EP 0 500 224).

Walker et al. teach an isothermal exonuclease mediated strand displacement method of claims 1, 20 amplification of a target nucleic acid wherein disclose that the method comprises

(a) hybridizing a first and second primer with first and second complementary nucleic acid fragments, with binding region at 3'-ends of the said target nucleic acid fragments and includes at its 5'-end a digestion resistant region (hemiphosphothiorate) (see co. 9, line 40-42, col. 5, line 37-57) wherein the target fragments include digestion resistant region (modified by an incorporation of modified nucleotide during primer extension), which allows only partial digestion of the primer by the enzyme having 5'-double strand specific exonuclease activity (see col. 9, line 26-39);

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(b) third and fourth primers having a degree of sequence homology (complementary) with first and second primers and bind at their 3' - ends (column 9, lines 43-48);

(c) providing an enzyme having strand displacing polymerase activity and enzyme having 5'-double strand specific exonuclease activity (exo<sup>-</sup> klenow DNA polymerase, Bst, or Bca) (see col. 8, line 29-58, col. 9, line 1-6); and

(e) dNTPs (including modified nucleotides) under conditions allowing hybridization, strand displacement polymerization thereby producing an amplified amount of the first and second strands (see col. 8, line 29-36, col. 9, line 18-39).

With regard to claim 2, Walker et al. also disclose that the method also comprises complementary DNA generated in situ from single stranded molecule (RNA) RNA (single stranded)(see column 6 lines 1-2);

With regard to claims 3-4, Walker et al. also disclose that the method comprises modified nucleotides and the modified nucleotides provide resistance to digestion by the exonuclease (see column 8, lines 29-36, col. 9, lines 22-26);

With regard to claims 5-6, 9, Walker et al. also disclose that primers comprise 15-100 nucleotides (see column 8, lines 15-20);

With regard to claim 10, Walker et al. teach that the 5' double-strand specific exonuclease is T7 gene 6 exonuclease (see col. 8, line 46-53);

With regard to claims 11, Walker et al. ('184) also disclose that the strand displacing DNA polymerase is selected from Klenow DNA polymerase, Bst DNA polymerase, (see column 8, , lines 54-58, col. 9, lines 1-6);

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With regard to claim 12, Walker et al. teach that the steps of exonuclease digestion and SDA are effectively separated by performing two separate reactions under conditions which favor the action of one or other enzyme (see col. 9, lines 18-39, indicates use of one enzyme at step to favor the action of one or the other at a time);

With regard to claim 13, Walker et al. teach that the reaction is effected isothermally (see col. 9, line 7-17);

With regard to claim 14, 21-22, Walker et al. teach that the digestable regions of first and second primers are of identical sequence and third and fourth primers are identical to those sequences and third primer binds to 3'-binding region of first primer and fourth primer binds to 3'-binding region of second primer (see col. 9, line 40-48);

With regard to claim 15, Walker et al. teach said 5'-ends of the primers are resistant to digestion by an exonuclease functioning as a single strand active exonuclease (polymerase) (see 8, line 54-58, col. 9, line 1-6);

With regard to claim 16, Walker et al. teach that the amplification occurs in the presence of further more primers (multiplex)(see col. 11, line 15-34, indicating use of one or more primers);

With regard to claim 17, Walker et al. teach that the method comprises a modified nucleotide incorporated into a growing nucleic acid chain is resistant to digestion (col. 8, line 29-45);

With regard to claim 18, Walker et al. teach that the nucleic acid is a DNA (see col. 8, line 1-2);

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With regard to claims 23-24, Walker et al. teach that the 5'-ends of primers are resistant to digestion by 5'-double strand specific exonuclease (see column 8, lines 29-36, col. 9, lines 22-26);

With regard to claims 25-26, Walker et al. also teach that the enzyme having strand displacement activity provides 5'- double-strand specific exonuclease activity (col. 8, line 54-58).

Thus the disclosure of Walker et al. meets the limitations in the instant claims.

***Response to arguments***

4. Applicants' response to the office action and amendment are fully considered and found persuasive in part.
5. With regard to the rejection made in the previous office action under 35 USC 112 second paragraph, applicants' amendment and arguments are fully considered and the rejection is withdrawn herein in view of the persuasive arguments.
6. With regard to the rejection made in the previous office action under 35 USC 102(b), Applicants' amendment and arguments are fully considered and the rejection is withdrawn herein in view of the persuasive arguments and new grounds of rejection.
7. With regard to the rejection made in the previous office action under 35 USC 103(a), Applicants' amendment and arguments are fully considered and the rejection is withdrawn herein in view of the persuasive arguments and new grounds of rejections.

***Conclusion***

No claims are allowable.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

*SPC*  
Suryaprabha Chunduru  
December 22, 2004

  
JEFFREY FREDMAN  
PRIMARY EXAMINER  
*12/22/04*